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such that less than 5% of the gene is degraded after exposure of said formulation to 1 U DNase I for 30 minutes in digestion buffer at 37°C.

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55. (Once Amended) A method of enhancing the therapeutic effect of a cell cycle blocking agent, or of lowering the dosage of a cell cycle blocking agent required for a therapeutic effect, administered to a patient ~~having cancer~~ comprising the steps of:

- (a) administering said cell cycle blocking agent to a patient; and
- (b) administering a foreign therapeutic gene to said patient within seven days of step (a), wherein said foreign therapeutic gene is fully encapsulated in a lipid formulation such that less than 5% of the gene is degraded after exposure of said formulation to 1 U DNase I for 30 minutes in digestion buffer at 37°C.

Please add new claims 56-77.

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56. (New) A method of enhancing the therapeutic effect of a cell cycle blocking agent, or of lowering the dosage of a cell cycle blocking agent required for a therapeutic effect, administered to a patient having cancer comprising the steps of:

- (a) administering said cell cycle blocking agent to a patient; and
- (b) administering a foreign therapeutic gene to said patient within seven days of step (a), wherein said foreign therapeutic gene is administered systemically.

57. (New) The method of claim 38 wherein cells are synchronized by contacting said cells with an amount of said cell cycle blocking agent that is effective to synchronize cells at said first stage of the cell cycle.

58. (New) The method of claim 57 wherein said cell cycle blocking agent synchronizes cells at a stage of the cell cycle when the nuclear membrane is substantially degraded.

59. (New) The method of claim 38 wherein said cell cycle blocking agent synchronizes cells at late S phase.

60. (New) The method of claim 38 wherein said cell cycle blocking agent synchronizes cells at the G₂/M phase boundary.

61. (New) The method of claim 38 wherein said cell cycle blocking agent synchronizes cells at a stage other than M phase, and the nucleic acid accumulates in cells that have cycled to the G₂/M phase boundary.

62. (New) The method of claim 38 wherein said cell cycle blocking agent is a vinca alkaloid.

63. (New) The method of claim 38 wherein said cell cycle blocking agent is cisplatin.

64. (New) The method of claim 38 wherein said cell cycle blocking agent is selected from the group consisting of taxol and taxolene.

65. (New) The method of claim 38 wherein said first stage and said second stage are the same.

66. (New) The method of claim 38 wherein the gene product of the therapeutic gene is toxic to the cell.

67. (New) The method of claim 66 wherein the gene product of the therapeutic gene induces apoptosis.

68. (New) The method of claim 38 wherein the nucleic acid is part of a lipid-nucleic acid particle.

Q3
Sub D² 69. (New) A method of enhancing the therapeutic effect of a foreign therapeutic gene administered to a patient having cancer, said method comprising the steps of:
(a) administering a cell cycle blocking agent to said patient; and
(b) administering said foreign therapeutic gene to said patient within seven days of step (a), wherein said foreign therapeutic gene is administered systemically.

70. (New) The method of claim 69, wherein said cancer comprises a tumor.

71. (New) The method of claim 70, wherein said cell cycle blocking agent and said foreign therapeutic gene are administered distal to the site of the tumor.

72. (New) The method of claim 69, wherein said cell cycle blocking agent or said foreign therapeutic gene are administered intravenously.

73. (New) The method of claim 69, wherein said cell cycle blocking agent or said foreign therapeutic gene are administered intraperitoneally.